

REMARKS

Claims 1 to 10 and 12 to 117 are pending in this application. Claim 11 was canceled in a previous amendment. Claims 4, 9, 13, 15, 20, 21, 24 to 27, and 30 to 115 were withdrawn from consideration. Claims 1 to 3, 5 to 8, 10, 12, 14, 16 to 19, 22, 23, 28, 29, 116, and 117 have been rejected. Applicant reasserts all prior arguments made in connection with the maintained rejections. Claim 1 has been amended, without conceding to the Examiner's characterization and without prejudice. No new matter has been added to claim 1; support for claim 1's amendments may be found *inter alia* at paragraph 2.

35 U.S.C. § 102

Suzuki

The Examiner rejected claims 1, 2, 5-8, 10, 12, 14, 17, and 18 under 35 U.S.C. § 102(b) as being anticipated by Suzuki JP 3-002124 ("Suzuki"). Applicant traverses this rejection for at least the reasons set forth in prior responses and the following reasons.

The Examiner set forth, in this rejection, "method steps are disclosed; mites [need] not be present, as there is no limitation in the claim body specifying the argued for excess, or infestation—the claimed step is shown by Suzuki." Further, the Examiner states, "Applicant argues the prior art fails to show mite treatment, but argues mites are always present. Examiner finds the claimed methods are of the instant invention." The Examiner has not understood Applicant's point that almost all, if not all, adult skin has some mites present and this normal level of mites does not cause any problems, however infestations (i.e. an excess amount) of mites in human skin can be very problematic and require treatment. Treating human skin does not equal treating infestations of mites, because not all human skin has an excess amount of (or is infested with) mites. This point is relevant to each of the maintained rejections.

Applicant notes that without conceding to the Examiner's characterizations, Claim 1 (and all of the other pending claims, which depend on Claim 1) was amended to refer to the infestation in the claimed step. Suzuki does not teach treating mite infestations, but rather acne treatments, which are not one and the same. (See The Merck Manual 811-814 (17th ed. 1999) a copy of which is attached hereto as Exhibit A). One of ordinary skill in the art would not find it obvious to use an acne treatment for mite infestation. Although all skin has some mites, the Examiner has not cited any evidence that mites cause acne or that all skin of acne patients is infested¹ with mites. The Examiner refused to provide an affidavit under 37 C.F.R. § 1.104(d)(2) in support of this inference. Because Applicant claims a method of treating excessive mites, not a method of treating acne or enhancing lotion product quality, Applicant respectfully requests that this rejection be withdrawn.

Harry's

The Examiner rejected Claims 1-3, 10, 12, 14, 17, and 18 under 35 U.S.C. § 102(a) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Harry's. Applicant traverses this rejection for at least the reasons set forth in prior responses and the following reasons.

Applicant respectfully disagrees that Claims 1-3, 10, 12, 14, 17, and 18 are anticipated by Harry's under 35 U.S.C. § 102(b). Claim 1 (and all of the other pending dependent claims) was amended without conceding to the Examiner's characterizations, and includes "mite infestations" in the claimed step. The Examiner asserted that, because Harry's teaches compositions useful for several skin ailments, Harry's automatically teaches a method

¹ Infestation by definition requires excessive mites, rather than the ordinary amount of mites on adult skin.

of treating excessive mites. Under 35 U.S.C. §102, all of the elements of the claim must be present in one reference for that claim to be anticipated. Although Harry's discusses several sulfur-containing compositions, Harry's specifically identifies these compositions for use in treating acne, oily skin, and sebum secretion. Harry's, p. 558-560. Harry's does not discuss the condition of excessive skin mites, the treatment of such, or the relationship between excessive mites and the skin disorders listed (acne, oily skin and sebum secretion). Mite infestation is a separate skin condition, and Harry's only teaches acne, oily skin, and sebum secretion treatments. Applicant submits that Applicant's claims are novel over Harry's because Harry's does not teach Applicant's invention of treating excessive mites. Applicant respectfully asserts that this rejection should be withdrawn.

Applicant also traverses the rejection that Claims 1-3, 10, 12, 14, 17, and 18 are obvious over Harry's under 35 U.S.C. § 103(a). The Examiner inferred that acne, oily skin, and sebum secretion are caused by mites, and again, neglected to provide a declaration under 37 C.F.R. § 1.104(d)(2). Mite infestation is a separate skin condition from acne, and Harry's only teaches acne, oily skin, and sebum secretion treatments. Given that acne is attributed to "an interaction among the hormones, keratin, sebum, and bacteria," and not mites (Exhibit A, The Merck Manual, 811-814), one of ordinary skill in the art would not find it obvious to use an acne treatment for mite infestation. Although all skin has some mites, the Examiner has not recited any evidence that mites cause acne, oily skin, or sebum secretion, and Harry's teachings are limited to acne, oily skin or sebum secretion treatments. Therefore, Applicant respectfully asserts that the Examiner's inference is unsubstantiated and, thus, the rejection should be withdrawn.

Bhagwat

Claims 10, 12, 14, 17-19, 22-23², 28 and 29 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,429,231 ("Bhagwat"). Applicant respectfully traverses the rejection for at least the reasons set forth in prior responses and the following reasons.

Applicant respectfully disagrees that Claims 10, 12, 14, 17-19, 22-23, 28, and 29 are anticipated by Bhagwat under 35 U.S.C. § 102(e) because Bhagwat does not teach Applicant's invention. Bhagwat discloses a composition for disorders "due to microbial infection or changes in normal keratinization, epidermal formation or pilosebaceous function, such as acne, psoriasis, seborrhea, rosacea, ingrown hairs and pseudofolliculitis barbae, and hyperpigmented skin, and cutaneous infection." Bhagwat, col. 1, lines 39-43. An infestation of mites is not synonymous with any of these disorders; a patient with any of these disorders does not necessarily have an infestation of mites. See Marks, Histopathology of Rosacea, 100 Arch. Derm., 683-691 (1969) ("Marks") (a copy of which is attached as Exhibit B), and Exhibit A, The Merck Manual. Although all, or almost all, adult skin (even healthy skin) has some mites, the Examiner has not pointed to any evidence that mites cause any of these disorders. Bhagwat does not anticipate all of the elements of Applicant's claimed invention. Therefore, Bhagwat's methods do not inherently or explicitly anticipate Applicant's invention. Thus, Applicant respectfully submits that this rejection should be withdrawn.

Milks

² Claims 20, 21, and 24-27 have been withdrawn, so we will not address these claims in connection with this rejection.

Claims 1-3, 10, 14, 16-19, 28, 29, 116, and 117 were rejected under 35 U.S.C. § 102(b) as being anticipated by Milks. Applicant respectfully traverses the rejection for at least the following reasons.

Applicant respectfully disagrees that Claims 1-3, 10, 14, 16-19, 28, 29, 116, and 117 are anticipated by Milks under 35 U.S.C. § 102(b). Milks specifically teaches that sulfur alone can be used to treat eczema, mange, and ringworm in veterinary medicine. Milks, p. 554. Nothing in Milks would suggest using this composition in human medicine or to treat humans, to which Applicant's invention is directed. Further, Milks does not teach mixtures of sulfur and a sulfur derivative. Instead, Milks discloses compositions with only one sulfur compound. Milks, p. 559. Milks does not anticipate every element of Applicant's claims. Applicant asserts that Applicant's invention is novel over Milks because Applicant's claimed invention utilizes a composition of sulfur, a sulfur derivative, and a carrier in the treatment of human skin which is infested with mites. Because Applicant does not teach using only sulfur as a treatment and is directed to human infested skin, Applicant's invention is novel. Applicant respectfully asserts that this rejection has been overcome.

35 U.S.C. § 103

Suzuki or Harry's in View of Bonnar, Lin, and Kligman

The Examiner rejected claims 1-3, 5-8, 10, 12, 14, and 16-20 under 35 U.S.C. § 103(a) as being obvious and unpatentable over Suzuki or Harry's in view of Bonnar, Lin et al, Sulfur Revisited, 18 J. Am. Acad. Dermatol., 553-558 (1988) ("Lin"), and U.S. Patent No. 4,752,472 ("Kligman"). Applicant traverses this rejection for at least the reasons set forth in the prior responses and the following reasons.

Applicant disagrees with the Examiner that Applicant's invention is obvious in light of the prior art. Applicant, again, notes that neither Suzuki nor Harry's teaches Applicant's claimed invention because neither reference teaches a remedy for mite infestations

in humans. The Examiner asserted that Lin teaches Applicant's invention of treating mite infestations with sulfur and sulfacetamide. This is incorrect. In Table III, Lin teaches only that sulfur, not sulfur derivatives, may be useful for "Demodectic eruptions." Lin, p. 555. Lin teaches nothing about the use of sulfur and sulfur derivatives (including sodium sulfacetamide) together for Demodex (mites). Table IV discloses no composition for treating mite infestations, and, instead, lists other disorders (acne, dandruff, etc.) having causes not linked to mite infestations. Lin, p. 556. The Examiner has refused to provide a reference or a declaration under 37 C.F.R. § 1.104 (d)(2) disclosing the alleged causal relationship between mites infestations and the disorders listed in Lin, Suzuki, or Harry's. Therefore, the Examiner has not met his prima facie burden.

Additionally, Applicant submits that the Examiner's use of Kligman still does not render the claimed invention obvious. Kligman merely discloses that products such as bacteria, fungi, and a mite contribute to follicular debris. Kligman, col. 1, lines 30-33. Kligman nowhere teaches or suggests that this debris causes skin disorders, as the Examiner alleged. Therefore, Kligman sheds no light on the causal relationship between excessive mites and skin disorders.

Applicant asserts that the Examiner's use of Bonnar to substantiate the causal relationship between skin disorders and the presence of excessive mites is also not persuasive. The Examiner correctly states that Bonnar discloses that all people have some mites on their skin. However, not all people have infestations of mites. Exhibit B, Marks, p. 683-691. Higher levels of mites might play a role in rosacea's pathogenesis. Bonnar, p. 443, emphasis added. However, not all rosacea patients have excessive mites and, therefore, mite infestation is a condition entirely separate from rosacea. Exhibit B, Marks, p. 690 (stating that evidence of fewer mites on skin afflicted with rosacea substantiates that mites are not a significant factor in causing rosacea). Therefore, the use of sulfur in treating skin disorders unrelated to mite

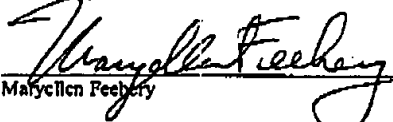
infestations in the cited art does not teach or suggest using compositions of sulfur and sulfur derivatives for treating mite infestations. Thus, Applicant's claimed invention is not obvious.

CONCLUSION

Applicant respectfully submits that the application is in condition for allowance.

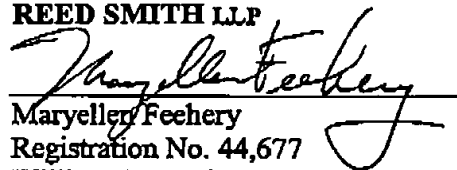
Applicant does not believe any additional fee is required for this Response and Request for Reconsideration, however, in the event any additional fee is required or any overpayment credit is due, the Commissioner is hereby authorized to charge Deposit Account No. 18-0586.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/022,476 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 703-872-9306 on the date shown below.


Maryellen Feehery

November 23, 2004
Date of Facsimile Transmission

Respectfully submitted,
REED SMITH LLP


Maryellen Feehery
Registration No. 44,677
William J. McNichol, Jr.
Registration No. 31,179
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
(215) 241-7988
Attorneys for Applicant